

PSJ17 Exh 116

**File Provided Natively**



# SOM and Current Cases

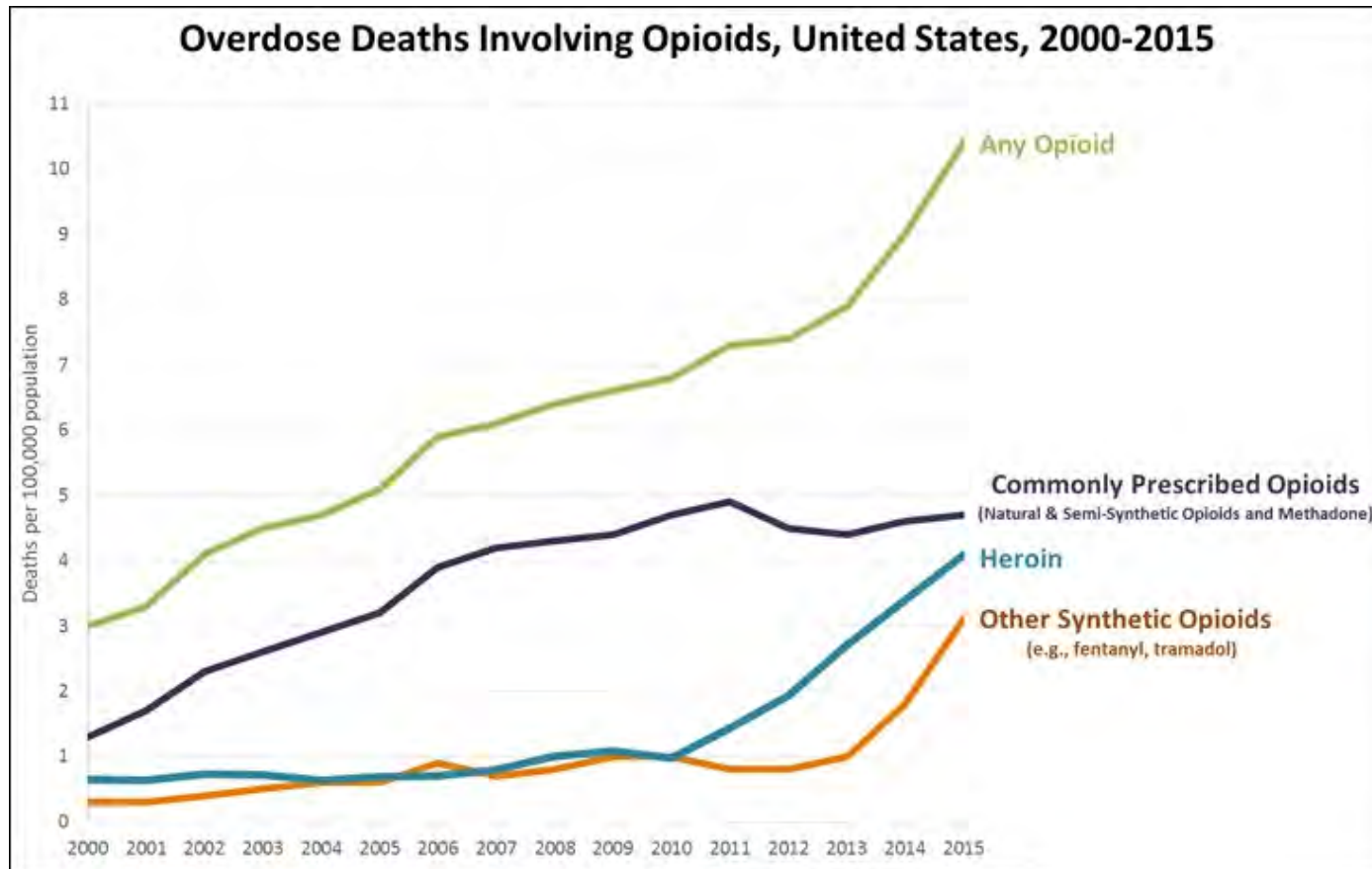
Joseph Tomkiewicz, DEA Compliance Manager

2017



TEVA

SOM





## SOM



### Orders Reported by Year

- 2014 - 1
- 2015 - 4
- 2016 - 0
- 2017 - 18, so far



## Recent Cases



### Red Flags



79188

Federal Register / Vol. 81, No. 218 / Thursday, November 10, 2016 / Notices

#### DEPARTMENT OF JUSTICE

#### Drug Enforcement Administration

[Docket No. 15–2]

#### Jones Total Health Care Pharmacy, L.L.C., and SND Health Care, L.L.C.; Decision and Order

On April 29, 2015, Administrative Law Judge Gail A. Randall (hereinafter, ALJ) issued the attached Recommended Decision.<sup>1</sup> Therein, the ALJ found that “Respondents violated recordkeeping requirements by failing to record whether Jones Pharmacy’s biennial inventory was taken at the opening or close of business, and by failing to indicate the number of tablets per opened commercial container, the number of tablets shipped in each commercial container, and the number of commercial containers that [were] on hand.” R.D. at 59 (citing 21 CFR

many of the prescriptions could not be resolved by the pharmacists. *Id.* at 64.

The ALJ specifically rejected Respondent’s contention that its owner (Ms. Chereese Jones) was simply naïve or unaware of various indicia (otherwise known as red flags) that the prescriptions her pharmacy filled lacked a legitimate medical purpose as well as its contention that during the relevant time period, Florida pharmacists were generally “unaware of the . . . concept of ‘red flags.’” R.D. at 66–69. The ALJ was unpersuaded by the testimony of Respondent’s Expert that pharmacists were generally unaware of the concept of red flags during the relevant time period, noting that while Respondent’s Expert claimed to have based her opinion on a review of the Agency’s administrative decisions, those decisions contradicted her testimony. *Id.* at 68–69.

Finding that the Government met its burden of proof, the ALJ then addressed

Having considered the record in its entirety including Respondent’s Exceptions, I find that while several of its contentions with respect to the ALJ’s factual findings are not without merit, I adopt the ALJ’s credibility findings and conclude that most of the ALJ’s factual findings are supported by a preponderance of the evidence. I further conclude that the ALJ’s factual findings support her legal conclusions that: (1) Respondent’s pharmacists dispensed numerous controlled substance prescriptions in violation of the Agency’s corresponding responsibility rule, *see* 21 CFR 1306.04(a); (2) Respondent has not accepted responsibility for its misconduct; and (3) that there is sufficient overlap in the ownership and control of Jones Pharmacy and SND Healthcare such that Jones’ misconduct supports the denial of SND’s application.<sup>2</sup>

Accordingly, I adopt the ALJ’s legal conclusions, as well as her implicit



## Recent Cases



### Computer Algorithms

**United States Court of Appeals**  
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued January 12, 2017

Decided June 30, 2017

No. 15-1335

MASTERS PHARMACEUTICAL, INC.,  
PETITIONER

v.

DRUG ENFORCEMENT ADMINISTRATION,  
RESPONDENT

On Petition for Review of a Final Order  
of the Drug Enforcement Administration



## Recent Cases



### Monitoring Our Customers

#### Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Tuesday, July 11, 2017

#### **Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations**

Mallinckrodt LLC, a pharmaceutical manufacturer and one of the largest manufacturers of generic oxycodone, agreed to pay \$35 million to settle allegations that it violated certain provisions of the Controlled Substances Act (CSA) that are subject to civil penalties, Attorney General Jeff Sessions of the Justice Department and Acting Administrator Chuck Rosenberg of the Drug Enforcement Administration (DEA) announced today.

This is the first settlement of its magnitude with a manufacturer of pharmaceuticals resolving nationwide claims that the company did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone in Florida and elsewhere. The settlement also addressed violations in the company's manufacturing batch records at its plant in Hobart, New York. Both sets of alleged violations impact accountability for controlled substances, and the compliance terms going forward are designed to help protect against diversion of these substances at critical links in the controlled substance supply chain.

"In the midst of one of the worst drug abuse crises in American history, the Department of Justice has the responsibility to





## Active Matters



### Current Affairs

## Sen. Claire McCaskill on the opioid epidemic: pharma “ought to begin looking over their shoulder”

The Democratic senator issues a warning to drug companies that contributed to the opioid epidemic.

Updated by German Lopez | @germanrlopez | [german.lopez@vox.com](mailto:german.lopez@vox.com) | Oct 11, 2017, 1:00pm EDT

TWEET

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Mark Wilson/Getty Images

Sen. Claire McCaskill (D-MO) says it's time for pharmaceutical companies to start worrying about their role in causing the **opioid epidemic**, the deadliest drug overdose crisis in US

### Most Read



America is facing an epistemic crisis





## Active Matters



### Current Affairs

**OPIOID  
NATION**

## Attorneys general from 41 states hit back against opioid-pumping big pharma firms



New York Attorney General Eric Schneiderman's office is among the 41 participating in the push to hold big pharma's feet to the fire. (SUSAN WATTS/NEW YORK DAILY NEWS)

TELEVISION

## Active Matters



### Current Affairs

**60 MINUTES** overtime



# MEET 60 MINUTES' DEA WHISTLEBLOWER

*Why has the country's opioid problem become a national emergency? A high-ranking whistleblower from the DEA explains how the drug industry--and Congress--fueled an epidemic*





## Suspicious Order Monitoring





# Suspicious Order Monitoring

2017

